Revised Sunshine Act deals pharma sharp blow by eliminating preemption of state laws

Final Senate bill drops preemption, lowers reporting threshold, and increases penalties

enators Charles Grassley (R-IA) and Herb Kohl (D-IA) introduced a revised version of the Physician Payments Sunshine Act late last week that effectively eliminates the preemption of state laws, which was the cornerstone of the industry's support for a draft version of the bill last year. This leaves drug and device companies facing the prospect of mandatory federal reporting requirements, as well as an ever-growing list of conflicting state law disclosure requirements. The final bill would also require drug and device companies to disclose aggregate payments to doctors in excess of \$100 a year, well below the \$500 threshold included in the draft version. It also increases the penalties for failing to disclose required information to the Department of Health and Human Services (HHS) from \$250,000 to \$1 million.

All sides agree that the industry's support of last year's draft bill was premised on the inclusion of a provision preempting state laws. In short, with calls for disclosure gaining momentum and eventual passage of the Sunshine Act considered likely, the industry opted to embrace a uniform federal law in place of a growing patchwork of conflicting state laws.

Clearly, the industry believed it had struck a compromise with the authors of the Senate bill. Now, the industry is left without a key Congressional ally on the issue of preemption. The House version of the Sunshine Act, introduced last year but yet to be introduced in this Congress, did not include such a provision.

• Cont. on page 2

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This leaves the industry in an awkward position, having praised the concept of disclosure in its endorsement of the draft bill last summer. The Pharmaceutical Research and Manufacturers of America (PhRMA) had little to say on the subject last week, noting only that it is "currently reviewing the legislation."

Stephen Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), was less vague in commenting on the revised bill. "AdvaMed and its member companies support the appropriate disclosure of payments made to physicians and were pleased to have supported S. 2029 as revised last year," said Ubl. "We are currently reviewing the details of this newly re-introduced legislation," he added, "but believe it is important that any federal disclosure legislation create a uniform national standard to prevent a patchwork approach by all 50 states."

By contrast, state activists immediately endorsed the revised bill. "The new version of the Act is a real improvement over last year's bill," said Maine Representative **Sharon Treat**, who heads the National Legislative Association on Prescription Drug Prices. "In particular," she said, "the language preempting similar state laws has been narrowed so that state disclosure and gift ban requirements that are more extensive than the proposed law may still be enforced."

A predictable turnabout

Last week's turnabout was, in fact, fairly predictable.

For months, we have been suggesting in these pages that it was hard to imagine Senators Grassley and Kohl disregarding the broad financial disclosure recommendations for drug and device companies that were considered and approved by the Medicare Payment Advisory Commission (MedPAC) last

year. The two Senators validated that theory by noting that the final bill incorporates "many of the new recommendations" made by the Commission.

MedPAC, an influential Congressional advisory group, was something of an unknown entity to much of the industry before it weighed in on financial disclosure for drug and device companies. However, several health care

Senator Grassley says he is considering MedPAC's recommendation that reporting requirements include payments to hospitals, pharmacists, CME groups, and others.

attorneys raised the specter that MedPAC's recommendations could have a significant impact on the final shape of the Sunshine Act. (For a complete discussion of this issue, see Rx Compliance Report, October 16, 2008 and November 17, 2008).

Epstein Becker & Green attorneys say changes will have big impact

According to attorneys at Epstein, Becker & Green, several key provisions in the Senate's proposed disclosure law have been modified from the previous versions of the draft bill.

Preemption. The proposed preemption language included in the legislation introduced last week now includes an additional paragraph acknowledging that certain state laws and regulations will not be preempted, says **Wendy Goldstein**, a partner with Epstein, Becker & Green in New York. "It is likely that numerous preemption interpretations could emerge," she adds, "and that will lead to inconsistent state law reporting by companies."

Penalties. The revised Sunshine Act also

increases the penalties for failing to report payments and other transfers of value, notes **Sara Giesting** of Epstein Becker & Green. For example, she says, the maximum aggregate penalty for "knowingly" failing to report payments was increased from \$250,000 to \$1 million per calendar year. "These penalties would provide the Secretary of HHS with significant tools for enforcing the Act," she says, "which we have not yet seen on a large scale by the states."

Exclusion. Manufacturers will be also challenged by the revised exclusions provision that removes the \$25 *de minimis* exception found in previous versions of the Act, says Goldstein. "Manufacturers will need a robust infrastructure in order to capture and report these payments," she says.

According to **Bill Sarraille**, a partner with Sidley Austin, the revised bill includes many—but certainly not all—of MedPAC's recommendations. Notably, he says, Grassley and Kohl limited the scope of the bill to disclosure of payments to physicians, rather than expanding it to include payments to additional entities, such as hospitals and advocacy groups, which MedPAC recommended.

However, as it stands, he points out, there is nothing in the legislation to preclude the states from passing legislation that includes those groups. "That could come in a piecemeal fashion in certain states, but not others, with different definitions, different reporting requirements, and different ways of calculating and allocating," he says. "This could be a disaster, in short order."

Moreover, Grassley flatly stated last week that he is considering MedPAC's recommendation that reporting requirements also be applied to industry payments to medical organizations, hospitals, pharmacy benefit managers, pharmacists and pharmacies, continuing medical education groups, and medical schools.

A mixed bag

The final version of the legislation is "a mixed bag," according to **Greg Levine**, a partner with Ropes and Gray in Washington, D.C. He says the final bill includes some helpful changes that will reduce the burden placed on the industry. For example, he says, while the draft bill called for quarterly reporting, the final bill requires only annual reporting.

Under the revised bill, companies would be required to begin annually reporting to HHS any "payment or other transfer of value" to a physician, physician medical practice, or physician group practice on March 31, 2011. The disclosure requirement is defined "expansively," according to Sarraille.

Specifically, it encompasses the following:

- payments of cash, in-kind items or services, or stock;
- fees for consulting or other services (including participation in continuing medical education);
- honoraria; food, travel, or entertainment payments;
- gifts or charitable contributions;
- grants and funding for education or research;
- royalties or licenses; and
- any other payment or transfer of value identified by the HHS Secretary.

These mandatory reports would also be required to include information about the recipient, the value and date of the payment or transfer, and a description of the payment or transfer, he adds.

Key exceptions

According to Sarraille, the final Senate bill includes some noteworthy exceptions to the disclosure requirement. For example, companies would not be required to report payments whose annual value totaled less than \$100 per recipient.

In addition, free product samples and educational

materials intended for patient use would be exempt from disclosure. "This is a significant deviation from MedPAC's recommendations, which would have collected information on free samples so that researchers could study their impact on providers' prescribing behavior," says Sarraille.

In addition, he says, manufacturers would be permitted to loan devices on a short-term basis and The Senate's disclosure bill does nothing to prevent states from passing piecemeal legislation with different definitions and reporting requirements, says Sidley Austin's Bill Sarraille.

to furnish items or services under a contractual warranty without triggering the reporting requirement.

The final Senate bill also tracks MedPAC's recommendations, he notes, by not requiring companies to report discounts, rebates, or in-kind items used to provide charity care.

State activists cite key changes

State activists wasted no time endorsing the revised bill. The key change, in their view, is undoubtedly the modified preemption provision. **Alan Coukell**, director of policy at The Prescription Project in Boston, argues that the *intent* of the current preemption requirement in the final Senate bill is similar to that of draft version circulated last summer. "The wording of this is better and tighter," he says. "This essentially prevents states from collecting the information the feds will collect.

However, it explicitly says that states can collect other information."

For example, he says, states could require companies to report how much they spend on DTC advertising, as West Virginia currently requires. Likewise, states could require companies to report payments to nurses, as Massachusetts recently proposed.

In addition, he points out, there is nothing in the bill that prevents states from simply prohibiting certain marketing practices, such as gifts over a certain size, as Minnesota and Massachusetts have done.

Another critical change in the legislation, says Coukell, is that if the marketing is linked to a specific drug or device, companies will have to list that drug or device. He says that will prove to be a useful research tool because the public will be able to correlate increased marketing with increased usage.

"We are still reading the bill line by line to understand all of its provisions, and there remain some concerns," says NLARX' Treat. For example, she says, the bill excludes nurses, nurse practitioners and physician assistants, who also prescribe and may receive gifts and payments. In addition, she says, it may be possible to evade the bill's provisions by making payments to intermediaries.

Numerous challenges

According to **Dan Kracov**, who heads Arnold & Porter's drug and device practice in Washington, D.C., as currently drafted, the Senate bill will be onerous for drug and device companies to implement. For example, he says, reducing the reporting threshold to \$100 is significant because it would potentially include many parties who receive a small honorarium or other nominal payments. "It is a real burden to pull this information together," he says, "so that is a significant change."

The implementation is also fairly rapid, says Kracov, considering the work required to implement an adequate reporting system. "Many of the companies have a lot of different streams of payments going to doctors," he points out.

In addition, says Kracov, there are some other categories that are specifically called out for disclosure, such as continuing medical education. It is unclear how that provision will actually work in practice, says Coukell, because companies will maintain that they merely give grants to third parties who then select speakers.

Finally, says Kracov, the aggregate payment reporting requirement, which is now set at \$500, will likely lead companies that have yet to establish a payment cap to take that step.

Strong prospects

All sides agree that some version of the Sunshine Act is likely to pass this year. One factor that could change the dynamic, says Kracov, is if physician groups mobilize in opposition to the inclusion of a provision that would require companies to report any ownership interest held by a physician or an immediate family member. These reports would be required to include the dollar amount invested by each physician, the value and terms of the investment, any payment or transfer of value to a physician holding an investment interest, as well as any other information deemed appropriate by the Secretary of HHS.

Is disclosure the midwife to elimination?

Proponents of disclosure of industry-physician financial relationships are fond of suggesting that sunlight is the best disinfectant." But there is little doubt that for many of drug marketing's most severe critics, disclosure of these activities should be the midwife to their elimination.

This fact was neatly captured in a *New York Times* editorial last month:

"Congress needs to pass legislation that would force all drug and medical-device companies to report a wide range of payments to doctors through a national registry so that all conflicts are known. Better yet, the medical profession needs to wean itself almost entirely from its pervasive dependence on industry money.

Treat echoed those sentiments last week. While endorsing the revised Senate bill, she argued the "best practice would be to ban these payments altogether," as Minnesota and Massachusetts have sought to do.

"We look forward to the day when the millions of dollars spent on such gifts and payments go instead to provide affordable medicines for all of our citizens," says Treat. ■

<u>Note</u>: Maine Rep. Sharon Treat will address the revised Sunshine Act along with Grassley aide Chris Armstrong as part of a timely audioconference Tuesday, February 10 (see p. 7 for details).

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Senator Charles Grassley (R-IA) has announced he plans to introduce a revised version of the much anticipated Physician Payments Sunshine Act early this year. On Tuesday, February 10, Chris Armstrong, Senator Grassley's key aide on this issue, will brief the industry on the latest version of the Sunshine Act and what it means for drug and device companies.

Also joining the 90-minute panel discussion will be Maine State Rep. Sharon Treat, a leading activist in the development of state marketing requirements for drug and device companies. Treat, who chairs NLARx, will review the ambitious state legislative agenda regarding gift bans, disclosure requirements, data mining restrictions, and other key initiatives.

Featured Faculty:

Christopher J. Armstrong, Esq.

Investigative Counsel, Committee on Finance, The Honorable Chuck Grassley, Ranking Member, United States Senate, Washington, DC

John T. Bentivoglio, Esq.

Partner, King & Spalding LLP, Former Special Counsel for Healthcare Fraud, Department of Justice, Washington, DC

Jennifer Colapietro

Director, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLC, Florham Park, NJ

Sharon Anglin Treat, Esq.

Maine State Representative, Executive Director, NLARx, Augusta, ME

Brian Riewerts

Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP, Washington, DC (Moderator)



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